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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,311	03/24/2006	Richard F. Ambinder	43369-103949	2676

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
07/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,311	AMBINDER ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,14 and 15* is/are rejected.

7)☒ Claim(s) *16-57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on April 02, 2009 have been noted. Claims 16, 22, 26, 30, 34, 38, 42, 46, 50, 54 have been amended. Claims 1-57 are pending. Claims 5-9 were withdrawn from consideration. Claims 1-4, 10-57 in the scope of the elected species of EBV LMP-2 and GM-CSF are considered.

Priority

1. The priority of claims 1-4, 10, 14-15 for the benefit of a prior-filed application under 35 U.S.C. 119(e) is still denied.

2. Applicants' argument has been respectfully considered; however, it is not persuasive, because the argument does not provide a detail support for the broadly claimed scope drawn to any human cell line except K562, which lacks MHC-I and MHC-II and express an antigen of EBV and any immunomodulator as the application was originally filed in the provisional Application No. 60,411,990, The priority of claims 1-4 and 10, 14-15 are only considered to be the effective filling date of PCT/US 03/29684, on Sept. 19, 2003. Applicants are encouraged to provide support in detail including the page and line etc.

Claim Rejections - 35 USC § 112 (Withdrawn)

3. The rejection of claims 16-57 under 35 U.S.C. 112, first paragraph for the scope of enablement issue has been withdrawn necessitated by Applicants' amendment.

Claim Rejections - 35 USC § 102 (Withdrawn)

4. The rejection of claims 1-4, 11-12, 14-15 under 35 U.S.C. 102(b) as being anticipated by Borrello et al. (Human Gen Therapy, 1999, Vol. 10, pp. 1983-1991) has been removed in view of Applicants' persuasive argument.

Claim Rejections - 35 USC § 103(Withdrawn)

5. The rejection of claims 1-4 and 10-57 under 35 U.S.C. 103(a) as being unpatentable over Borrello et al. (Human Gen Therapy, 1999, Vol. 10, pp. 1983-1991) and Lee et al. (J. Immunol. 1997, Vol. 158, pp. 3325-3334) has been removed necessitated by Applicants amendment and persuasive argument.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 10, 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicants do not have a possession for the generic human cell line that lacks MHC-I and MHC-II and expresses any EBV antigen in combination with any immunomodulator as the application was originally filed.

3. To determine whether Applicants have a possession for the claimed subject or the claimed subject matter lacks of a written description, it is considered based on 1). Full coverage of the claimed scope of invention; 2). Whether applicant provides sufficient support to support the full scope of the invention and 3). Whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing according to the disclosure of the entire application. This should include the following aspects of the considerations: a. Actual reduction to practice; b. Disclosure of drawings or structural chemical formulas; c. sufficient relevant identifying characteristics including i). Complete structure, ii). Partial structure; iii). Physical and/or chemical properties and iv). Functional characteristics when coupled with a known or disclosed correlation between function and structure; d. Method of making the claimed invention; e. Level of skill and knowledge in the art; f. Predictability in the art.

4. For a claim drawn to a genus, consideration needs also focusing on each of the above factors to determine whether there is disclosure of a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. The number of species required to represent a genus will vary, depending on the level

of skill and knowledge in the art and the variability among the claimed genus. For instance, fewer species will be required where the skill and knowledge in the art is high, and more species will be required where the claimed genus is highly variable.

5. In the instant case, claims 1-4, 10 and 14-15 are drawn to a genus of human cell line that lacks MHC-I and MHC-II and expresses an antigen of EBV and any immunomodulator.

6. Based on specification, Applicants do not show reduction to the practice for any other human cell lines except K562 for deficiency in MHC-1 and MHCII, but expressing an EBV antigen and an immunomodulator. It is concluded that one skilled in the art would recognize that the applicants were in possession of the claimed invention as a whole at the time of filing according to the disclosure of the entire application.

7. MPEP § 2163.02 states, "[a] n objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

8. Because the claims encompass a genus of human cell lines, an sufficient evidence needs to be provided for a reduction of practice prior to the current application was originally filed and at least a representative number of species for such claimed human cell lines that had been isolated by actual reduction to practice.

9. Absent a detailed and particular description of a representative number, or at least a substantial number of such human cell lines, a skilled artisan could not immediately recognize that Applicants had the claimed genus of human cell lines. The full breadth of the claims does not meet the written description and enablement provision of 35 U.S.C. 112, first paragraph.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nickol Gary can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648

Search Notes (continued)

Application/Control No.	Applicant(s)/Patent under Reexamination	
10/528,311	AMBINDER ET AL.	
Examiner	**Art Unit**	
BAO LI	1648	

SEARCHED			
Class	Subclass	Date	Examiner
435	320	7/14/2009	BLI

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
435	**320**	**7/14/2009**	**BLI**
EAST, WEST		7/14/2009	BLI

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
double patenting search updated	7/14/2009	BLI
EAST, WEST, STN, MEDLINE	7/14/2009	BLI